February 25, 2008

Reconsideration is requested.

Claims 12-22, 27 and 28 are pending. Claims 15, 27 and 28 have been canceled above, without prejudice. A detail of claim 15 has been added to amended claim 12, without prejudice. New claim 29 finds support throughout the specification, such as on page 3 in the paragraph spanning lines 16-21. No new matter has been added. The claim amendments are not believed to raise new issues requiring further consideration and/or search. Entry of the present Amendment is requested.

Upon entry of the present Amendment, claims 12, 13, 16-22 and 29 will be pending.

The Examiner is requested to return a PTO 892 listing the cited WO03/017992, to complete the record.

The Section 102 rejection of claims 12-22, 27 and 28 over Petyaev (WO 03/017992), is traversed. Reconsideration and withdrawal of the rejection are requested in view of the following distinguishing comments.

Petyaev (WO03/017992) discloses the treatment of atherosclerotic conditions through the inhibition of the lipid oxidation activity of anti-Chlamydia abzymes. Azithromycin and aspirin are two examples of anti-Chlamydia abzyme inhibitors which are proposed for use either individually or in combination to treat atherosclerotic conditions.

The Examiner is understood to believe that patients with atherosclerotic conditions as disclosed by Petyaev include patients with a disorder of lipid metabolism Ivan PETYAEV

Appl. No. 10/574,852

Attv. Ref.: 620-433

Amendment After Final Rejection

February 25, 2008

and therefore that the methods of the unamended claims allegedly treat the same patients with the same composition to produce inherently the same result as Petyaev.

Hyperlipidemia is known to be a risk factor for atherosclerosis. This is confirmed by Petyaev, which states on page 37 lines 9-13 that:

> Changes in the lipoprotein profile and the elevation of the total cholesterol in plasma/serum are the only specific risk factors established for atherosclerosis. However, these changes can be detected for only 10-15% of all patients with clinical complications of this disease.

The applicants submit that a risk factor for a disease is not the same as the disease itself. The applicants submit that a person who has a risk factor for a disease simply has an increased likelihood of suffering from a disease relative to the population as a whole. The incidence of people having the risk factor who subsequently develop the disease may be very low and it is by no means inevitable or even probable that a person who has a risk factor for a disease will go on to develop the disease.

Equally, a person without the risk factor may still develop the disease.

The applicants believe that an individual may have hyperlipidemia and not have an atherosclerotic disorder. Conversely, an individual may have an atherosclerotic disorder without having hyperlipidemia.

Furthermore, Petyaev is understood by the applicants to state that only a small proportion (10-15%) of all patients with clinical complications of atherosclerosis have hyperlipidemia. In other words, 85-90% of all patients with clinical complications of atherosclerosis do not have hyperlipidemia. Thus, a large majority of individuals with an atherosclerotic disorder do not have hyperlipidemia. In addition, the applicants believe

Ivan PETYAEV

Appl. No. 10/574,852

Attv. Ref.: 620-433

Amendment After Final Rejection

February 25, 2008

that Petyaev lacks any teaching of an association between hyperlipidemia and the anti-

Chlamydia abzyme activity which correlates with atherosclerotic disorders.

The applicants submit that since only a small fraction of patients with atherosclerotic disorders display hyperlipidemia, it will be appreciated by one of ordinary skill in the art that the instant claims do not relate to the treatment of the same patients as Petyaev and the methods disclosed by Petyaev do not include the treatment of

patients with hyperlipidemia.

Furthermore, hyperlipidemia is not inherently treated in the methods of Petyeav.

MPEP 2112 IV states:

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. In re Rijckaert, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993)

In the present case, the fact that an individual with an atherosclerotic disorder characterized by high abzyme levels may have hyperlipidemia is not sufficient to establish that the treatment of hyperlipidemia is inherent in the disclosure of Petyaev.

The present specification teaches a different technical effect to that taught in Petyaev. Petyaev teaches that anti-Chlamydia abzymes are a causative factor of atherosclerosis and that inhibition of anti-Chlamydia abzyme activity is useful in treating atherosclerotic disorders.

By contrast, the present specification teaches that the combination of an antimicrobial agent and a metal chelator reduces the levels of total cholesterol and ApoB in patients. This different technical effect allows the treatment of a different group of patients, namely individuals with hyperlipidemia.

- 6 -

1306324

Ivan PETYAEV

Appl. No. 10/574,852

Attv. Ref.: 620-433

Amendment After Final Rejection

therefore not anticipated by Petyaev et al.

February 25, 2008

There is no disclosure in Petyaev of the treatment of an individual with a recognized need for treatment of hyperlipidemia with a combination of an anti-microbial compound and metal chelator. Nor is such treatment inherent in the treatment of patients with atherosclerotic disorders, as taught by Petyaev. The instant claims are

Withdrawal of the Section 102 rejection of the claims over Petyaev, and entry of the present Amendment, are requested.

The claims are submitted to be in condition for allowance and a Notice to that effect is requested. The Examiner is requested to contact the undersigned in the event anything further is required in this regard.

Respectfully submitted,

NIXON & VANDERHYE P.C.

/B. J. Sadoff/ By: _____ B. J. Sadoff Reg. No. 36,663

BJS:

901 North Glebe Road, 11th Floor

Arlington, VA 22203-1808 Telephone: (703) 816-4000 Facsimile: (703) 816-4100